United States Department of Energy
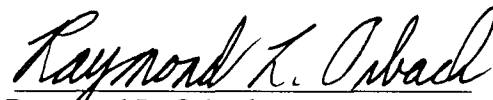
Office of Science
Quality Assurance Program
July 2006

Headquarters
Office of Science
Quality Assurance Program
July 2006

This Office of Science (SC) Headquarters (HQ) Quality Assurance Program (QAP) is applicable to all SC HQ elements, facilities, and personnel until superseded by a later approved QAP. All questions and errors should be brought to the attention of Matt Cole at 301-903-8288 or matt.cole@science.doe.gov

Approved: *Raymond L. Orbach*   Date 8/1/06

Raymond L. Orbach
Under Secretary for Science

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Introduction

The Office of Science (SC) is committed to assuring the quality of its products and the safety of its operations. This Quality Assurance Program (QAP) describes how the Office of Science manages its work in accordance with the criteria in DOE Order O 414.1C, "Quality Assurance", and the International Organization for Standardization's (ISO's) Standard 9001-2000 on Quality Management Systems.

The Office of Science is a multifaceted organization that funds research to produce knowledge and is involved in research at the leading edge of science. This research relies on the efforts of thousands of dedicated people in laboratories and the offices that support them including relationships with researchers all over the world. This QAP only captures the means by which we strive for the quality of our science in the broadest sense.

This Quality Assurance Program describes the means by which the Office of Science ensures that:
 a) Senior management provides planning, organization, direction, control, and support to achieve SC objectives;
 b) Quality is achieved and maintained;
 c) Environmental, safety, and health (ES&H) risks and impacts are minimized, while maximizing reliability and performance;
 d) A management system is in place that is consistent with the principles and functions of DOE's Integrated Safety Management System and ES&H Oversight Directives, and
 e) Each SC program and office reviews, evaluates, and improves its overall performance and that of its contractors.

Recognizing that the same principles affecting quality also affect safe and environmentally clean and sustainable operations, the integration with the Office of Science's implementation of Integrated Safety Management is described herein.

Each quality criterion in both the DOE Order 414.1C and the ISO 9001-2000 Standard is addressed in the context of the Office of Science's work.
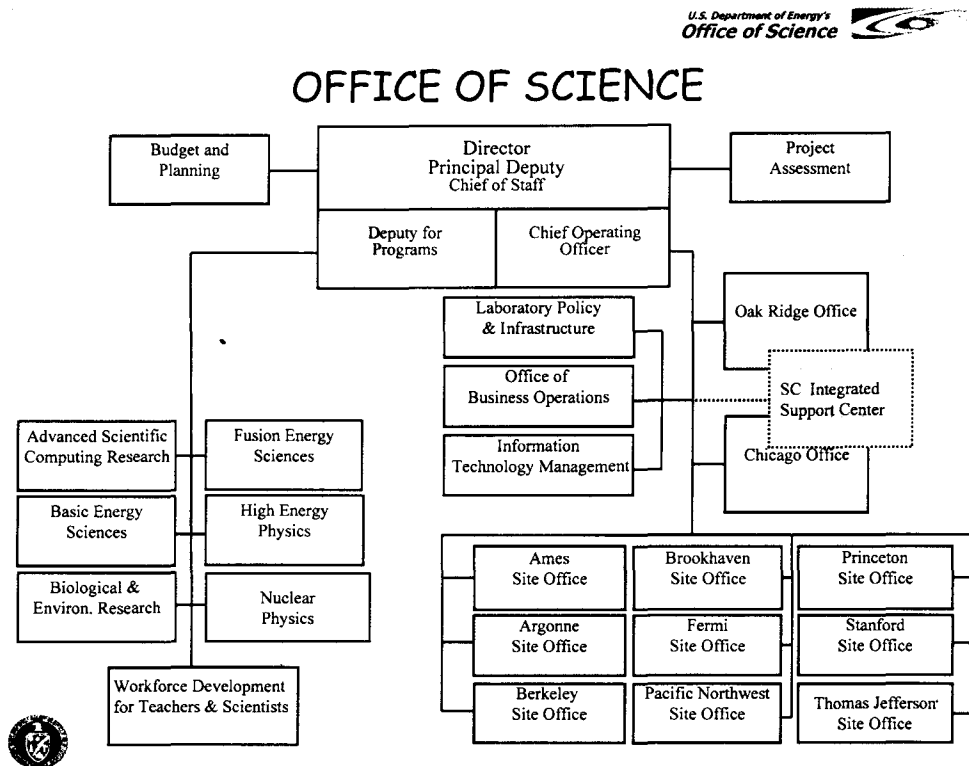

Office of Science Overview

The following is an overview of the work of the Office of Science, taken from the SC web site:

http://www.science.doe.gov/about/index.htm

The Office of Science:

- is the single largest supporter of basic research in the physical sciences in the United States, providing more than 40 percent of total funding for this vital area of national importance. It oversees – and is the principal federal funding agency of – the Nation's research programs in high-energy physics, nuclear physics, and fusion energy sciences.

- manages fundamental research programs in basic energy sciences, biological and environmental sciences, and computational science. In addition, the Office of Science is the Federal Government's largest single funder of materials and chemical sciences, and it supports unique and vital parts of U.S. research in climate change, geophysics, genomics, life sciences, and science education.

- manages this research portfolio through six interdisciplinary program offices: Advanced Scientific Computing Research, Basic Energy Sciences, Biological and Environmental Research, Fusion Energy Sciences, High Energy Physics and Nuclear Physics. In addition, the Office of Science sponsors a range of science education initiatives through its Workforce Development for Teachers and Scientists program. Supporting these program offices are several staff offices.

- makes extensive use of peer review and federal advisory committees to develop general directions for research investments, to identify priorities, and to determine the very best scientific proposals to support.

- manages 10 world-class laboratories, which often are called the "crown jewels" of our national research infrastructure. The national laboratory system, created over a half-century ago, is the most comprehensive research system of its kind in the world.

- oversees the construction and operation of some of the Nation's most advanced research and development user facilities, located at national laboratories and universities. These include particle and nuclear physics accelerators, synchrotron light sources, neutron scattering facilities, supercomputers and high-speed computer networks.

- is a principal supporter of graduate students and postdoctoral researchers early in their careers. Almost 50 percent of its research funding goes to support research at more than 300 colleges, universities, and institutes nationwide.

- reaches out to America's youth in grades K-12 and their teachers to help improve students' knowledge of science and mathematics and their understanding of global energy and environmental challenges.

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The organization of the Office of Science is shown in the chart below:

U.S. Department of Energy's
Office of Science

OFFICE OF SCIENCE

Budget and Planning	Director Principal Deputy Chief of Staff	Project Assessment

Deputy for Programs	Chief Operating Officer

Laboratory Policy & Infrastructure

Office of Business Operations

Information Technology Management

Oak Ridge Office

SC Integrated Support Center

Chicago Office

Advanced Scientific Computing Research	Fusion Energy Sciences
Basic Energy Sciences	High Energy Physics
Biological & Environ. Research	Nuclear Physics

Workforce Development for Teachers & Scientists

Ames Site Office	Brookhaven Site Office	Princeton Site Office
Argonne Site Office	Fermi Site Office	Stanford Site Office
Berkeley Site Office	Pacific Northwest Site Office	Thomas Jefferson Site Office

The Budget and Planning office reports to the Office of the Director, as does the Project Assessment office.

The Deputy Director for Programs is responsible for the six interdisciplinary program offices that fund research and facilities to perform that research. The Workforce Development office also falls under this authority.

The Chief Operating Officer manages the Headquarters offices that are responsible for ES&H Policy, Safeguards and Security, Laboratory Policy, Infrastructure Management, Business Operations, and Information Technology; the ten SC Site Offices, and the Integrated Support Center Offices located at Chicago and Oak Ridge.

The Office of Science Headquarters programs and offices work with the SC Site Offices, laboratories, and other supported researchers, providing funding and direction for research and operations.

Quality Assurance Program Scope

This QAP applies to the management of SC work at its Headquarters offices and to the interactions of Headquarters offices with SC Site Offices; the Integrated Support Center (ISC), and the researchers, laboratories, and institutions which SC supports. Work done at the SC Integrated Support Center and Site Offices is covered under their own QAP's.

Configuration Management

This document is issued, updated, and controlled by the Office of Science's Environment, Safety, and Health Division - SC-31.1. Questions and suggestions for improving the SC QAP should be submitted to:

U.S. Department of Energy
Office of Laboratory Policy and Infrastructure
SC-31/GTN
Washington, DC 20585-1290

Quality Policy

The Office of Science will provide world class quality products and services that meet or exceed our customers' requirements in a safe, secure, and cost effective manner.

Quality Objectives

To achieve the goals set forth in its Quality Policy, the Office of Science will:

- use a customer-focused, process-based approach to managing its work,

- use a factual approach to decision-making, and

- continually improve its products and work processes.

Organization, Mission, Functions, Responsibilities, and Authorities

The documentation describing the Office of Science organization, mission and all related responsibilities and authorities aspects is located on the web site shown below that describes the status of the SC re-engineering effort, otherwise known as "OneSC":

The principle benefit of this QAP is in the continuing high quality of the science from the funding SC provides; improving the support, direction and oversight provided to the Office of Science site offices, laboratories, and supported researchers, and improving the bi-directional interactions between Headquarters and those entities external to it. There is little physical "product" procured at the Headquarters level other than information technology equipment.

Responsibilities

The responsibilities and authorities for implementing the mission of SC are established by the SC Mission and Functions Statement located on the OneSC web site. The high level responsibilities specifically related to aspects of implementing this QAP are listed in the following table.

QAP Implementation Responsibilities

SC Position	Responsibility and Authority
Director	• Defines the Quality Policy, • Establishes Quality Objectives, and • Ensures the communication and understanding of the Quality Policy and Objectives throughout the organization. • Ensures that the Office of the Director implements the provisions of this QAP
Deputy Director for Programs	• Ensures that SC-sponsored research follows established peer review methods to ensure its high quality, • Ensures that SC Program offices implement this QAP
Chief Operations Officer	• Serves as the Senior Official in charge of maintaining, coordinating and implementing the SC QAP, • Ensures that Headquarters offices under the Chief Operating Officer, implement this QAP, • Provides direction on development and implementation of ISC and Field QAP's • Ensures that the Integrated Support Center, and the Site Offices submit QAP's consistent with this QAP for approval, • Chairs regular reviews of the suitability and effectiveness of the SC QAP, • Coordinates improvements to the QAP, and • Approves SC Field Element QAP's

SC Position	Responsibility and Authority
Program Associate Directors and Office Directors	• Implement the provisions of the QAP within their offices, • Ensure that products and services satisfy customer requirements including quality, safety, cost, schedule, performance, reliability, durability, accuracy, and maintainability, and • Ensure that personnel comply with applicable standards, regulations, specifications, and documented procedures.
Site Office Managers	• Review and approve contractor QAP's.
All personnel	• Operate in conformance with applicable standards, regulations, specifications, and documented procedures, and • Stop work in progress or make appropriate notifications when unsafe conditions exist or requirements are not being met.

Office of Science Management Systems

The framework of documents for the specific management of the Office of Science in its OneSC restructuring effort is currently being developed and will be contained in a web-based system of SC Management Systems (SCMS). These Management Systems are currently found on the web site: http://scms.sc.doe.gov/

The current list of systems being developed is:
> Budget Execution
> Budget Formulation
> Communications and Stakeholder Interactions
> Emergency Management
> Environment, Safety and Health
> Financial Assistance Management System
> Financial Management and Integrity
> Human Resources Services
> Information Technology
> Legal Services
> Management and Operating (M&O) Contracting
> Non-M&O Contracting
> Personal Property
> Program Management
> Project Management
> Quality Assurance
> Real Property
> Records Management
> Requirements Management
> Safeguards and Security

Safety Management and Quality Assurance

The principles of Quality Assurance and the DOE Integrated Safety Management (ISM) System are embedded in all Office of Science activities. In conducting its mission, it is the policy of the Office of Science to ensure the safety and protection of workers, the public, and the environment; the quality of its work; and the continuity of its scientific activities. The Office of Science strives to effectively plan, budget for, execute, and evaluate its activities such that work is done correctly and safely without having to perform re-work. It is also SC policy that quality, environmental, and safety requirements for products and services be clearly defined before work begins. Work processes are continuously monitored, assessed, and improved in the Office of Science to achieve a rising standard of excellence in the quality and safety of our programs, projects, products, and services.

Implementation of Quality Assurance Criteria and Integrated Safety Management Principles and Functions

This section describes the means by which the ten DOE Quality Assurance Criteria in DOE O 414.1C, as grouped in three categories: Management, Performance, and Assessment, are implemented within the Office of Science. The criteria from ISO 9001-2000 and the DOE's Integrated Safety Management System are included and discussed in the appropriate places in this QAP as well to demonstrate their means of inclusion in the work of the Office of Science. These criteria are applied in a manner graded or "tailored" to fit the situation in the Office of Science Headquarters, which is described later in this QAP.

Section A. Management

1. DOE Criterion: Quality Assurance Program

ISO 9001-2000 Criteria: All

ISM: Line Management Responsibility for Safety
ISM: Clear Roles and Responsibilities

> DOE Requirement:
>
> A written Quality Assurance Program (QAP) must be developed, implemented, and maintained. The QAP must describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. The QAP must describe management processes, including planning, scheduling, and resource considerations.

This document is the Office of Science's Quality Assurance Program; within it are contained descriptions of or references to all of the means by which the criteria in ISO 9001-2000 are addressed.

It describes the organization of the Office of Science; its function and mission; and how the quality of its work is assured through implementation of the ten DOE QA Criteria and the use of the ISO 9001-2000 quality management system criteria as well. It also describes the inclusion of the Integrated Safety Management Systems Functions and Principles into the SC Quality Assurance Program.

The sequence and interaction of SC work processes and the means by which SC determines that these processes are effective will be described in detail in the SC Management Systems which are currently under development.

The Office of Science òperates under applicable federal and state laws, regulations, Executive Orders, administration policies, DOE Orders, and internal requirements. These are too numerous to mention or describe in one single document. Each SC program office documents the requirements under which it conducts its work.

Customer Focus and Agreements

The Office of Science is committed to being the entity of choice for those researchers who wish to perform cutting edge science. All documentation necessary to establish agreements with the customers of SC research and customers who depend on the availability of SC facilities will be described in the SC Management Systems.

Interfaces with Other DOE Organizations

SC interfaces with Office of Security and Safety Performance Assurance (SP) when that office performs assessments of SC facilities or programs.

- The Chief Operating Officer's organization (SC-3) is the primary interface with oversight and safety organizations on matters of nuclear safety.

- The Environment, Safety, and Health Division (SC-31.1) has the primary interface with the Office of Environment, Safety, and Health (EH) for assistance with assessments, lessons learned/operating experience documentation, and QA-related support in overseeing SC sites.

- Issues are discussed with other DOE Program and Staff offices as necessary to ensure coordination and consistency

2. DOE Criterion: Personnel Training and Qualification

ISO 9001-2000 Criterion: Resource Management - Competence, Awareness, and Training

ISM: Competence commensurate with responsibilities

DOE Requirement:

Personnel must be trained and qualified to ensure they are capable of performing their assigned work. Continuing training and education is necessary to ensure that job proficiency is maintained.

The Office of Science uses standard DOE and Office of Personnel Management processes to hire persons qualified to perform their jobs. For further training and educational needs, SC uses the process outlined in DOE Order 360.1, "Federal Employee Training." All Office of Science employees have Individual Development Plans (IDP's) that describe the training and education needs for their work. These IDP's are tailored to the needs of the employee and the office in which the employee works. The implementation of this effort is a line management responsibility within each SC office. Training is a criterion for both safety and quality assurance.

3. DOE Criterion: Quality Improvement

ISO 9001-2000 Criterion: Measurement, Analysis, and Improvement – all criteria

ISM: Feedback and Improvement

DOE Requirement:

Processes to detect and prevent quality problems must be established and implemented. Items, services, and processes that do not meet established requirements must be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction must include identifying the causes of problems and working to prevent recurrence. Item characteristics, process implementation, and other quality-related information must be reviewed and the data analyzed to identify items, services, and processes needing improvement.

Each SC office establishes and maintains its own methods of improving the quality of its work. The Office of Science is in the process of restructuring, and several internal organizations are guiding that effort. Further means of quality improvement will be developed as the SC Management Systems are better established.

The SC Environment, Safety, and Health Division (SC-31.1) identifies and communicates product quality and safety issues to SC Site Offices. Resources such as the Government-Industry Data Exchange Program (GIDEP) and the DOE Operating Experience program are used to learn about safety and quality issues.

Feedback

Feedback occurs through assessments of the Headquarters programs and other internal efforts to improve work. Results of these efforts are communicated to SC Management and used to improve the operation of SC facilities. Processes involving feedback are being further documented in the SC Management Systems under development.

Improvement

Results of efforts to improve efficiency or quality of work are implemented at various levels within SC according to the work done. The OneSC Restructuring effort is implemented through the Office of the Director, for example. Other efforts may be implemented at lower levels.

Actions that arise out of accident investigations or findings from Office of Security and Safety Performance Assurance (SP) assessments are recorded and tracked using the DOE Corrective Action Management Plan (CAMP). Actions not rising to that level of attention are tracked internally using the SC "DocLog" system to provide for prompt and thorough answering of correspondence. Actions are tracked by the responsible organization within Science. All other findings for SC assessments are documented and tracked by the SC organization performing the review/assessment. Reports generated are formalized and retained in each respective office's files. The SC Operating Experience Coordinator will interact with each organization to assist in developing operating experience information from the assessments, as appropriate, for the Office of Science.

4. DOE Criterion: Documents and Records

ISO 9001-2000 Criteria:
Quality Management System – Control of Documents
Quality Management System – Control of Records

DOE Requirement:

Documents must be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records must be specified, prepared, reviewed, approved, and maintained.

The Office of Science maintains records in accordance with DOE Order 200.1, Information Management Program, which discusses and references all of the requirements for records management. All requirements for records management are found at the following DOE web site:

http://cio.doe.gov/RBManagement/Records/records.html

Section B. Performance

5. DOE Criterion: Work Processes

ISO 9001-2000 Criteria:
Customer Communication – all process-related criteria
Product Realization – Customer-related processes

ISM: Balanced priorities
ISM: Identification of safety standards and requirements
ISM: Work Planning
ISM: Operations Authorization
ISM: Implement hazard controls
ISM: Perform Work within Controls

DOE Requirement:

Work must be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means. Items must be identified and controlled to ensure their proper use. Items must be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection must be calibrated and maintained.

The Office of Science's processes are primarily documented at this time in its program offices. The SC programs develop their processes and control them. The processes which are SC-wide include such things as budget formulation and the research grant processes. These SC-wide processes are being formalized through development of the SC Management Systems.

The processes in the Office of Science themselves do not involve work that includes hazards, such as would be the case for physical work in a facility. The identification and control of hazards in the Office of Science work is performed by the individual program offices, such as in the development of unique hazard controls for nanoscience work or other research.

The Office of Science follows the DOE Project Management Orders for the design, construction, and startup of its facilities. The Office of Science provides federal program and project managers to perform the oversight of contractor design efforts. These processes are found at the SC Office of Project Assessment's (SC-1.3) web site:

http://www.science.doe.gov/opa/

The Office of Science has customers at several levels. In some regard, the science community as a whole is a customer of the work of SC, and more specifically, the

researchers who benefit from the safe and efficient operation of its facilities. The Office of Science has users who depend on the scientific facilities being available for their research. Direct agreements are executed with these persons at the laboratory level for work performed in SC facilities. The Office of Science is a customer for the research it funds; it does execute agreements with funding recipients as to the expectations for the funding received.

6. DOE Criterion: Design

ISO 9001-2000 Criterion: Customer Communication – all criteria under Design and Development

ISM: Define the Scope of Work
ISM: Identification of Safety standards and requirements
ISM: Analyze Hazards
ISM: Hazard Controls Tailored to Work Being Performed
ISM: Develop Hazard Controls

DOE Requirement:

Items and processes must be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, must incorporate applicable requirements and design bases. Design interfaces must be identified and controlled. The adequacy of design products must be verified or validated by individuals or groups other than those who performed the work. Verification and validation work must be completed before approval and implementation of the design.

The Office of Science Headquarters is involved in the design of its facilities through its project management process. Information on this process is located at:

http://www.science.doe.gov/opa/

This process will be further defined through the SC Management Systems that are being developed.

7. DOE Criterion: Procurement

ISO 9001-2000 Criterion: Customer Communication - Purchasing

ISM: Identification of safety standards and requirements

DOE Requirement:

Procured items and services must meet established requirements and perform as specified. Prospective suppliers must be evaluated and selected on the basis of specified criteria. Processes to ensure that approved suppliers continue to provide acceptable items and services must be established and implemented

One of the major "products" procured in SC is scientific research. The requirements for the conduct and performance of research are well established and are documented on the Office of Science web site in multiple locations. "Suppliers" of research, i.e., those principle investigators and the institutions in which they perform research for SC, are evaluated by the peer review process in order to both obtain and continue work for SC.

Acquisition of Facilities

The Office of Science also funds the construction of research facilities. Our processes for the design and procurement of facilities are described in the web site of our Office of Project Assessment at:

http://www.science.doe.gov/opa/

Acquisition of Information Technology Equipment

The Office of Science procures information technology equipment for its Headquarters offices, in accordance with all DOE Chief Information Officer (CIO) and Federal procurement requirements. Specification, acceptance testing, and installation are performed by the SC Office of Information Technology Management.

8. DOE Criterion: Inspection and Acceptance Testing

ISO 9001-2000 Criteria:
Customer Communication - Product Identification and Traceability
Customer Communication -Verification of Purchased Product
Customer Communication - Control of Monitoring and Measuring Devices
Measurement, Analysis, and Improvement - Control of Nonconforming Product

DOE Requirement:

Inspection and testing of specified items, services, and processes must be conducted using established acceptance and performance criteria. Equipment used for inspections and tests must be calibrated and maintained.

The Office of Science Headquarters does not procure items for systems which are critical for the safety of its nuclear facilities. The inspection and testing of equipment procured for the use of SC Headquarters offices is handled by the office procuring the equipment.

The Office of Science does procure information systems hardware and software. The processes for the performance of these procurements are handled by the Office of the Science Information Officer.

The Office of Science also procures basic office supplies and furniture. Defective items are handled through the normal return processes of the vendors from which the items were purchased.

Section C. Assessment

9. DOE Criterion: Management Assessment

ISO 9001-2000 Criteria:
Management Responsibility – Management Review of the Quality Management System
Measurement, analysis, and improvement

ISM: Feedback and Improvement

DOE Requirement:

Managers must assess their management processes. Problems that hinder the organization from achieving its objectives must be identified and corrected.

Management assessments of programs in the Office of Science are conducted in many forms by each individual office. Further plans are being developed for management assessment of Office of Science Operations.

10. DOE Criterion: Independent Assessment

ISO 9001-2000 Criteria:
Management Responsibility – Management Review of the Quality Management System
Measurement, analysis, and improvement

ISM: Feedback and Improvement

DOE Requirement:

Independent assessments must be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. The group performing independent assessments must have sufficient authority and freedom from the line to carry out its responsibilities. Persons conducting independent assessments must be technically qualified and knowledgeable in the areas assessed. Other forms of independent assessment also exist, such as reviews by "Committees of Visitors" who are researchers external to SC that review SC science programs.

Independent assessment of the Office of Science is the responsibility of the DOE Office of Security and Safety Performance Assurance.

Software Quality Assurance

The Office of Science Headquarters makes limited, if any, use of safety software for the design of or review of the safety bases for nuclear facilities or other safety analysis purposes. Any software intended for such use would first be reviewed by persons competent in the field of software quality assurance and nuclear safety engineering to ensure that all the current DOE software quality assurance requirements are met.

Other software used at SC Headquarters meets applicable software quality requirements as established in multiple DOE and federal information management rules, directives, and orders.

Management of Suspect or Counterfeit Items (SCI)

The SC Headquarters offices do not disposition items found that may be suspect or counterfeit. The SC Environment, Safety, and Health Division maintain awareness of SCI found at SC sites through the Occurrence Reporting and Processing System and communications from the SC Site Offices. Any significant issues are brought to the attention of the Director of the Office of Science by the cognizant Site Office Manager.

Application of a Graded Approach Concept

All of the criteria in this document are applied to situations based on the "graded approach" concept, as defined in the DOE Order O 414.1C and referenced in the Definitions section of this document. The application of quality or safety requirements is commensurate with the risk involved. Risk is a function of probability of occurrence and consequence of occurrence. For example, the risk involved by not applying strict product inspection procedures to office supplies is that of having to take time to exchange defective products for new ones should a defect be encountered. The risk involved in making an error in the data quality of an environmental assessment dealing with drinking water can have much more profound consequences and thus deserves much more attention.

Appendix A – Explanations of Integrated Safety Management Guiding Principles and Core Functions

GUIDING PRINCIPLES

Line Management Responsibility for Safety. Line management is directly responsible for the protection of the public, the workers, and the environment. As a complement to line management, the Department's Office of Environment, Safety and Health provides safety policy, enforcement, and independent oversight functions.

Clear Roles and Responsibilities. Clear and unambiguous lines of authority and responsibility for ensuring safety shall be established and maintained at all organizational levels within the Department and its contractors.

Competence Commensurate with Responsibilities. Personnel shall possess the experience, knowledge, skills, and abilities that are necessary to discharge their responsibilities.

Balanced Priorities. Resources shall be effectively allocated to address safety, programmatic, and operational considerations. Protecting the public, the workers, and the environment shall be a priority whenever activities are planned and performed.

Identification of Safety Standards and Requirements. Before work is performed, the associated hazards shall be evaluated and an agreed-upon set of safety standards and requirements shall be established which, if properly implemented, will provide adequate assurance that the public, the workers, and the environment are protected from adverse consequences.

Hazard Controls Tailored to Work Being Performed. Administrative and engineering controls to prevent and mitigate hazards shall be tailored to the work being performed and associated hazards.

Operations Authorization. The conditions and requirements to be satisfied for operations to be initiated and conducted shall be clearly established and agreed-upon.

CORE FUNCTIONS

Define the Scope of Work. Missions are translated into work, expectations are set, tasks are identified and prioritized, and resources are allocated.

Analyze the Hazards. Hazards associated with the work are identified, analyzed and categorized.

Develop and Implement Hazard Controls. Applicable standards and requirements are identified and agreed-upon, controls to prevent/mitigate hazards are identified, the safety envelope is established, and controls are implemented.

Perform Work within Controls. Readiness is confirmed and work is performed safely.

Provide Feedback and Continuous Improvement. Feedback information on the adequacy of controls is gathered, opportunities for improving the definition and

planning of work are identified and implemented, line and independent oversight is conducted, and, if necessary, regulatory enforcement actions occur.

Appendix B – Quality Assurance Criteria Relationship with Integrated Safety Management

The quality assurance criteria in this QAP and their implementation at SC Headquarters level do not duplicate the functions and principles of Integrated Safety Management. Line management responsibilities are clearly delineated in SC, including the responsibility for safety. Standards and requirements are identified. Systems exist to provide for training and education to ensure competence. Processes are in place to establish priorities for work; establish hazard controls for work; and authorize work. Processes are in place to define how the scope of work is developed and how all the hazards associated with that work will be identified and controlled. Since most of the work at the Headquarters level is broad and conceptual in nature, these processes fulfill the ISM functions and Quality Assurance criteria through the lower-tiered Safety Management Systems and QAP's at the sites where the work we fund will be performed. It is the SC stated expectation in all our work that safety is a priority.

Appendix C - References

10 CFR 830, DOE Nuclear Safety Rules

American Society for Mechanical Engineering (ASME) Standard NQA-1-2000, "Nuclear Quality Assurance"

DOE Order 200.1, Information Management Program

DOE P 226.1, Department of Energy Oversight Policy

DOE O 226.1, Implementation of Department of Energy Oversight Policy

DOE Order O 414.1C, Quality Assurance

DOE P 450.4, Safety Management System Policy

DOE M 411.1-1C, Safety Management Functions, Responsibilities, And Authorities Manual

DOE Policy 413.1, Program and Project Management Policy for the Planning, Programming, Budgeting and Acquisition of Capital Assets

Office of Science, NEPA Compliance Officer Communication 94-04, Rev. 1, July, 2000, "Quality Assurance Plan for Environmental Assessments"

ISO 9001-2000, "Quality Management Systems"

Office of Science Merit Review System for Research, Federal Register 91-5680, effective March 11, 1991, as described at: http://www.sc.doe.gov/grants/merit.html

Office of Science Mission and Function statements and Organization Chart:
http://www.screstruct.doe.gov/secretarial_approval.html

Office of Science Records Management requirements:
http://cio.doe.gov/RBManagement/Records/records.html

SC Office of Project Assessment processes:
http://www.science.doe.gov/opa

Appendix D - Acronyms

CAMP	Corrective Action Management Plan
CFR	Code of Federal Regulations
DOE	United States Department of Energy
ES&H	Environment, Safety, and Health
HQ	Headquarters
IDP	Individual Development Plan
ISO	International Organization for Standardization
ISMS	Integrated Safety Management System
M	Manual
O	Order
QA	Quality Assurance
QAP	Quality Assurance Program
SC	Office of Science
SO	Secretarial Officer

Appendix E – Definitions

Assessment. A review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.

Configuration Management. The process of identifying and defining the configuration items in a system (i.e., software and hardware), controlling the release and change of these items throughout the system's life cycle, and recording and reporting the status of configuration items and change requests. (ASME NQA-1-2000)

Graded Approach. The process of ensuring that the levels of analyses, documentation, and actions used to comply with requirements is commensurate with (10 CFR 830)

(1) the relative importance to safety, safeguards, and security;

(2) the magnitude of any hazard involved;

(3) the life-cycle stage of a facility or item;

(4) the programmatic mission of a facility;

(5) the particular characteristics of a facility or item;

(6) the relative importance to radiological and non-radiological hazards; and

(7) any other relevant factors.

Item. An all-inclusive term used in place of appurtenance, assembly, component, equipment, material, module, part, structure, product, software, subassembly, subsystem, system, unit, or support systems. (10 CFR 830)

Integrated Safety Management. Is an inclusive set of principles and functions developed by DOE to establish effective management systems for safe operations.

Nuclear Facility. A reactor or a nonreactor nuclear facility where an activity is conducted for or on behalf of DOE and includes any related area, structure, facility, or activity to the extent necessary to ensure proper implementation of the requirements established by 10 CFR 830. (10 CFR 830)

Process. Series of actions that achieve an end result. (10 CFR 830)

Quality. The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations. (10 CFR 830)

Quality Assurance. Actions that provide confidence that quality is achieved. (10 CFR 830)

Quality Assurance Program. The overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work. (10 CFR 830)

Safety. An all-inclusive term used synonymously with environment, safety, and health to encompass protection of the public, the workers, and the environment.

Safety Software. Includes the following.

    (1) Safety System Software. Software for a nuclear facility that performs a safety function as part of a structure, system, or component and is cited in either

        (a) a DOE approved documented safety analysis or

        (b) an approved hazard analysis per DOE P 450.4, Safety Management System Policy, dated 10-15-96, and the DEAR clause.

    (2) Safety and Hazard Analysis Software and Design Software. Software that is used to classify, design, or analyze nuclear facilities. This software is not part of a structure, system, or component (SSC) but helps to ensure the proper accident or hazards analysis of nuclear facilities or an SSC that performs a safety function.

    (3) Safety Management and Administrative Controls Software. Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or technical safety requirements or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment as addressed in 10 CFR 830, 10 CFR 835, and the DEAR ISMS clause.

Service. Work, such as design, construction, fabrication, decontamination, environmental remediation, waste management, laboratory sample analysis, safety software development/validation/testing, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, training, assessment, repair, and installation or the like. In the context of this QAP, the term "product" also includes "service." (10 CFR 830)

Software. Computer programs, procedures, and associated documentation and data pertaining to the operation of a computer system. (NQA-1-2000)

Suspect/Counterfeit Item (S/CI). An item is suspect when inspection or testing indicates that it may not conform to established Government or industry-accepted specifications or national consensus standards or whose documentation, appearance, performance, material, or other characteristics may have been misrepresented by the supplier or manufacturer. A counterfeit item is one that has been copied or substituted without legal right or authority or whose material, performance, or characteristics have been misrepresented by the supplier or manufacturer. Items that do not conform to established requirements are not normally considered S/CIs if nonconformity results from one or more of the following conditions (which must be controlled by site procedures as nonconforming items):

  (1) defects resulting from inadequate design or production quality control;

  (2) damage during shipping, handling, or storage;

  (3) improper installation;

  (4) deterioration during service;

  (5) degradation during removal;

  (6) failure resulting from aging or misapplication; or

  (7) other controllable causes.

Work. A defined task or activity such as research and development; operations; environmental remediation; maintenance and repair; administration; safety software development, validation, testing, and use; inspection; safeguards and security; or data collection and analysis.